

K251780 iGPS Navigation InstrumentsSep 15, 2025
97 days to decisionK251780 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k251780/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 10, 2025
Decision date	Sep 15, 2025
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SI-BONE, Inc.
Location	Santa Clara, CA, US
Contact	Jayasri Prabakaran
Website	https://si-bone.com
510(k) history	32 submissions · 32 cleared · 2008-2026

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